

Remarks

Of the 32 (per preliminary amendment of June 15, 2006) claims, nine have been cancelled (9-12, 14, 27, 30-32) and two have been previously added. Applicants add six new claims with this amendment. Support for new claims 35 to 40 can be found, e.g., in the claims they depend on. Support for the amendment to claim 15, 18, 24 and 25 can, e.g., be found on page 4, lines 25-27 and page 5, lines 8-32, in particular lines 29 to 32 as they relate to the preceding description as well as, e.g., page 7, lines 16-26. Support for the amendments to claims 28 and 29 can be found, e.g., on page 11, lines 15-21 and page 11, line 36 to page 12, line 2, respectively. Claims 1 and 33 are in independent form.

35 U.S.C. 112, SECOND PARAGRAPH REJECTIONS

On page 2, the Office rejected claims 2, 3, 7, 13, 21 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 2 and 3, the term "the target entity" is said to lack antecedent basis after the term's omission from claim 1. Recitations in claims 7, 13, 21 and 25 (2 occurrences) of "preferably", are said to render portions of the respective claims indefinite and ambiguous.

In response, applicants amended any reference in the claims to "target entity" to "nucleic acid" in accordance with claim 1. The recitations in claims 7, 13, 21 and 25 (2 occurrences) after the term "preferably" were separated out into new claims (35 to 40).

35 U.S.C. §102(e) REJECTION

Starting on page 2, the Office rejected claims 1-3, 5, 7, 13 and 33 under 35 U.S.C. 102(e) as being anticipated by PG PUBS Document US 2005/0244882 to Gauch et al (hereinafter "Gauch").

Gauch is said to disclose all limitations of the rejected claims.

During the above memorialized interview, in which applicants suggested to limit the polymer/composite material to one that comprises one or more polymerized anionic monomers, the Office noted that para [00178] of Gauch, which discloses a superabsorbent layer 14 also contains a reference to acrylate and cited U.S. Patent 6,855,434 to Romasn-Hess et al. which was said to teach at column 1, lines 25-40 that ionic superabsorbent polymers may be either anionic (eg. acrylate based) or cationic in nature so as to absorb relatively large amounts of water. Applicants have further amended claim 1 to introduce in the alternative the limitations of claim 24 and 25, which should render this rejection moot.

35 U.S.C. §103(a) REJECTION

On page 4, the Office rejected claim 8 under 35 U.S.C. 103(a) as being unpatentable over Gauch in view of US Patent 4,902,559 to Eschwey et al. (hereinafter "Eschwey").

The Office acknowledged that Gauch does not disclose that the superabsorbent materials are swollen as the target entity is separated from solution, but referred to Eschwey, column 1, lines 7-16, column 4, lines 1-24, for this element.

The rejection has become moot due to the incorporation of the limitations of 24 and 25 into claim 1.

Also on page 4, the Office rejected claims 15-26, 28, 29 and 34 under 35 U.S.C. 103(a) as being unpatentable over Gauch in view of Eschwey in combination with PGPUBS US 2002/0193030 to Yao et al (hereinafter "Yao") and PGPUBS US 2004/0029166 to Fan.

The Office acknowledged in the Action, that Gauch does not teach that his superabsorbing material comprises polymer containing vinylic monomers and anionic, cationic and/or zwitterionic monomers such as surfactants. This opinion was adjusted in the above memorialized interview. The Office also referred in the Action to Eschwey (column 3, lines 57-67) for such a disclosure as well as to Yao for teaching superabsorbent composite copolymers for laboratory, including nucleic acid sample collection and analysis (paragraphs 9,18-20, 44 and 45). Fan is also said to provide such a disclosure (paragraphs 33...49-52). Yao is said to teach inclusion of charged or neutralized (zwitterionic) sorbent fibers (paragraphs 74-77).

The Office concluded that it would have been obvious to one of ordinary skill in the arts of assaying nucleic acid-containing samples to have utilized the superabsorbent polymers taught by Eschwey, Yao and Fan, so as to effectively sorb and bind the variety of biological and chemical contaminants having differing charges that may be present, in addition to effectively binding the nucleic acids, until addition of selective elution solvent.

With regard to claims 24 and 25, the Office referred to Fan which was said to teach various size particles of the superabsorbent, thus powdery or bead-like material at paras [0046] to [0048].

Applicants note that the Office relied for the disclosure of a "superabsorptive material" in Gauch on the collector 12, the sponge-like material 13 and the superabsorbent layer 14 as shown Gauch's Fig. 2 (Office Action, page 2, lower part). Here Gauch shows an embodiment that is described as a

"funnel-shaped isolation device 10 which contains a collector 12, which in turn contains a sponge-like material 13 that serves to absorb the lysis and washing buffers. Under the sponge-like material 13, the superabsorbent layer 14 may be

placed to improve the suction performance. Alternatively, layer 14 may also contain a material which is chemically able to react with water, e.g., acrylate. The water is therefore also removed from the process. Lysate or another preparation of nucleic acids is placed in the funnel. The sponge-like material 13 absorbs the applied liquid through membrane 11. Prior to the addition of the elution buffer, the sponge is moved some distance from the membrane, e.g., by a mechanism inside a collector 12 (not visible in the drawing). This will prevent the elution buffer in the last stage from being also suctioned through membrane 11. This buffer, however, stays on the surface (FIG. 2b) and can be removed together with the nucleic acids from above.” (para [00178], *emphasis added*)

First of all, applicants respectfully submit that from the above it appears that the use of acrylate is considered by Gauch as an alternative of a superabsorbent material and not as part of the superabsorbent material as interpreted by the Office.

In addition, the presently claimed invention (claim 1) is directed at a method of concentrating and purifying a nucleic acid in a liquid sample, said method comprising **contacting said liquid sample . . . comprising said nucleic acid . . . with a superabsorbent polymer or a superabsorptive composite material to absorb at least a portion of the sample . . . , wherein, upon said contacting, the solvent is more efficiently sorbed than the nucleic acid and the sample is concentrated.** (*emphasis added*)

The original claim language made clear that the liquid sample that is contacted with the superabsorbent polymer or a superabsorptive composite comprises a nucleic acid (compare also the language of claim 3). However, claims 1 and 33 have been amended to further emphasize this point.

From the description of Gauch's Fig. 2b, it becomes clear that any liquid containing nucleic acid is placed on the top of the membrane 11, which in turn is in contact with the sponge-like material 13, underneath which the superabsorbent material 14 is placed. The nucleic acid stays, as can be inferred from the description of Fig.2b in para [00178] on top of the membrane 11. Thus, neither the superabsorbent material 14 nor the sponge-like material 13 of Gauch come into contact with a liquid sample comprising a nucleic acid, but only with a liquid sample from which the nucleic acid has been separated.

Applicants also note that Fan is, as stated in Fan's para [0010] to [0013], directed at a method for separating nucleic acids comprising

- 1) bringing a sample containing nucleated cells into contact with a lysis solution,
- 2) bringing the sample containing nucleated cells into contact with a water-insoluble solid-phase carrier having an average particle size of 0.01 to 1000 μm . . . to adsorb and bind nucleic acids released from the nucleated cells onto the surface of the solid-phase carrier, and
- 3) separating the solid-phase carrier from the sample.

Fan clarifies at different places that the nucleic acid is to be deposited on this solid-phase carrier, namely that the nucleic acid is adsorbed (para [0001], [0043]) on the surface of this carrier.

Starting in para [0044] Fan describes his solid carrier in more detail. Paragraph [0049] states that the solid-phase carrier is preferably made of "synthetic polymers, inorganic substances, and glass." In paragraph [0051] the solid carrier is referred to as a "water-insoluble solid-phase carrier" and in para [0053] Fan describes how to improve the hardness of this solid phase.

Paragraphs [0046] to [0048] cited by the Office and the specific particle sizes referred to therein, refer to these solid-phase carriers that have little in common with the "superabsorbent polymer or a superabsorptive composite material" as claimed. In fact, applicants having reviewed Fan's paragraphs [0033] to [0052] as cited by the Office on page 4 of the Action, submit their belief that Fan does not make therein any reference to a "superabsorbent composite copolymer" or a similar term (see wording of Action).

Applicants note that (1) the acrylate containing material as disclosed in Gauch appears to be an alternative to the superabsorbent material disclosed by Gauch rather than being a part of it, that (2) superabsorbent material 14 and the sponge-like material 13 as disclosed in Gauch is not contacted with a liquid sample comprising said nucleic acid as set forth in the present claims and that (3) Fan's solid-phase carriers appear to have neither absorbent or absorptive properties as claimed. Rather Fan's carriers are solid and designed to adsorbed nucleic acid and thus are unsuitable for a set up as described by Gauch Fig. 2. In fact, using Fan's beads in Gauch's set up as shown in Figure 2, would not only defeat the purpose that Gauch seeks to accomplish with his superabsorbent material 14/sponge-like material 13, but also the purpose of Fan since no nucleic acid could reach Fan's beads in Gauch's set up as shown in Fig. 2.

Applicants submit that using Fan's beads in Gauch's design would render Gauch unsatisfactory for its intended purpose. Thus, there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicants also submit that there is no motivation to use the bead design described as preferred in Fan for use in adsorbing nucleic acid, as a guidance for the design of superabsorbent/absorptive material. Applicants submit that there would have been no good reason for the person of ordinary skill in the to pursue a bead or pulver design for the a superabsorbent material of layer 14 in Gauch (compare MPEP §2143 E. "Obvious To Try" - Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success).

For the reasons provided above, applicants submit that no *prima facie* case of obviousness has been established for claims 1 and 33 as amended herein, or any claim dependent thereon.

In view of the above, applicants sincerely believes that the claims are now in condition for allowance. However, if any issue remains, the Office is urged to call the undersigned at **301-657-1282** to seek a speedy resolution of such issue.

The Commissioner is authorized to charge any fee deficiencies and overpayments to deposit account number 50-3135.

Respectfully submitted,

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